LASERTAINMENT PRODUCTIONS INTERNATIONAL

7883 '99 AUG 24 P1:32

August 18, 1999

Mr. Frank Mackison
Center for Devices & Radiological Health
Office of Compliance (HFZ-342)
2098 Gaither Road
Rockville, MD 20850

RE: VARIANCE 86V-0194 RENEWAL REQUEST

Dear Mr. Mackison:

Please accept this letter as a request to renew our Variance #86V-0194, expiration date October 16, 1999.

There are no changes to be made at this time and we would like to request a renewal period of four years, if possible. I have enclosed a copy of our current Variance if this will be of assistance.

If you have any questions or concerns, please contact me at 651-633-8000. Thank you.

Sincerely,

Lynn A. Sweet

Lynn A. Sweet, L.A.
Lasertainment Productions, Inc.

Enc.

cc: HFA-305

8xP5

1901 OAKCREST AVENUE, SUITE #1
MINNEAPOLIS, MN 55113-2617 (USA)
PHONE: 651-633-8000
FAX: 651-633-8083
E-MAIL@LASERTAINMENT.COM
WWW.LASERTAINMENT.COM

86V-0194

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 20 1998

Ref: FDA Docket No. 86V-0194
Accession No. 86A0466-15

Mr. Robert M. Teorey
President
Lasertainment Productions International
1901 Oakcrest Avenue, Suite 1
Roseville, Minnesota 55113

Dear Mr. Teorey:

In accordance with 21 CFR 1010.4(c)(1) notice is given that the petition of Lasertainment Productions International, dated April 6, 1998, for an amendment to their variance, Number 86V-0194, from 21 CFR 1040.11(c) of the performance standard for laser products is approved. This variance will allow the introduction into commerce of the laser light show products described in paragraph D below.

A. Variance Number

86V-0194

B. Effective Date

In accordance with 21 CFR 1010.4(c)(1), this variance shall become effective on the date of this letter.

C. Termination Date

This variance shall be terminated on October 16, 1999.

D. Product for Which Variance is Granted

This variance is granted for the Class IIIb or IV Lasertainment Productions International (LPI) Model LTCP-1 Series, LPI Model LTBT Series, and LPI 360 laser projectors and light shows assembled and produced by LPI. The laser light shows may incorporate the firm's projectors or certified Laser Images CS Series and Laser Fantasy Model Rainbow and Infinity Laser Beam Series laser projection systems. The projectors will contain certified helium-neon, argon, krypton, argon/kryptron, and/or frequency-doubled Nd:YAG lasers.

This amendment will also permit the sale, loan, or lease of the LPI Model LTCP-1 Series, LPI Model LTBT Series, or Laser Fantasy Model Rainbow and Infinity Series projectors provided such actions satisfy the requirements of Paragraph 4 of Attachment A of this variance.

The laser light shows will be presented in temporary or permanent installations in planetariums, theaters, discotheques or night clubs, classrooms, and outdoor unenclosed areas for any contracted duration.

The effects employed may be front or rear screen projections, multiple reflection/diffraction effects, reflections from stationary mirrors, stationary or scanning irradiation of rotating mirror balls, fiber optic projections, cone and tunnel effects, and enhanced scattering effects.

E. Provision from Which Variance is Granted

This variance is granted from 21 CFR 1040.11(c) of the performance standard for laser products requiring that each demonstration laser product shall comply with all of the applicable requirements of 21 CFR 1040.10 for a Class I, IIa, II, or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.

F. Conditions under Which Variance is Granted

In lieu of the requirements referred to in Item E above, the conditions as specified below in Variance Attachment A and Variance Attachment B shall apply to the products and devices manufactured under this variance and to the shows assembled and produced under this variance.

G. Basis for Approval of Variance

In accordance with 21 CFR 1010.4(a)(2), it has been determined that the product is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting the requirements referred to in Item E. Suitable means of radiation safety and protection will be provided by constraints on the physical and optical design, and by warnings in the user/purchaser information.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state: This product complies with performance standards for laser products under 21 CFR Part 1040 except with respect to those characteristics authorized by Variance Number 86V-0194 effective October 16, 1986.

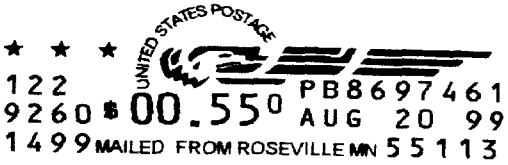
This variance action is available for public disclosure in the Food and Drug Administration (FDA) Dockets Management Branch and a notice of availability will be published in the Federal Register. The variance will remain in effect until the termination date unless a determination is made that the variance should be amended or withdrawn to protect the public health and safety.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: FDA Dockets Management Branch, Docket No. 86V-0194

Attachments A and B



FIRST CLASS MAIL

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Food and Drug Administration
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